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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,489	05/25/2000	Ray W. Wood	029318/0596	7761

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EXAMINER	
QAZI, SABIHA NAIM	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/577,489	WOOD ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *28-40,42-45 and 47-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *28-40,42-45 and 47-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Substance of Interview including description of the general nature of what was discussed: Examiner spoke to Ms. Simkin about the IDS filed on 5/18/05 after the brief. It will not be considered. If in case the case is re-opened than Examiner will consider the references. Examiner told Ms. SImkin that there may a possibility to make a new rejection, in case any relevant prior art found. . .

Non-Final Office Action

Acknowledgement is made of the response filed on 12/17/04. Claims 28-40, 42-45 and 47-59 are pending. No claim is allowed.

- The 35 USC § 103(a) rejections over US 5747001 (WIEDMANN et al), US 6264922 (WOOD et al.), and US 5145684 (LIVERSIDGE et al.) is withdrawn as a terminal disclaimer has been filed for WEIDMANN et al. and the arguments are found persuasive.
- The double patenting rejection over WOOD et al stands, as the Applicants have failed to file a terminal disclaimer. The Examiner notes that the Remarks filed on February 4, 2004 state (on page 14) that a terminal disclaimer has been filed for *both* WEIDMANN et al and WOOD et al; however, there is no terminal disclaimer for WOOD et al on record. Therefore, this rejection stands until the Applicants file a terminal disclaimer for WOOD et al.
- Upon further review and search the rejection over JAMES and LIVERSIDGE et al is withdrawn and new rejections are being made. Finality of the rejection s withdrawn.
- Applicants arguments that "JAMES is directed to water-soluble active agents, so JAMES and LIVERSIDGE et al do not provide motivation to prepare insoluble active agents. Because JAMES teaches aerosols but not poorly water-soluble active agents and LIVERSIDGE et al teaches poorly water-soluble drugs but not aerosols, there is no motivation to combine JAMES and LIVERSIDGE et al" was

fully considered and therefore now reference is used which teach aerosols for poorly soluble drugs.

Double Patenting – WOOD et al

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28-40 and 42-45 are rejected under the judicially created doctrine of double patenting over claims 24-30 of WOOD et al since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:

Claims 24-30 of WOOD et al are drawn to a method of treating a mammal comprising delivering a composition of nanoparticles to lungs, a composition that is instantly claimed is considered obvious for delivering an aerosol containing nanoparticles.

There is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application, which matured into a patent. See MPEP § 804.

Double Patenting – SAIDI et al

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28-40, 42-45 and 47-59 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-24 of SAIDI et al (U.S. Patent No. 6,241,969). Although the conflicting claims are not identical, they are not patentably distinct from each other because SAIDI et al is drawn to compositions containing corticosteroid compounds as active agents for the treatment of ailments and diseases of the respiratory tract, particularly the lungs through inhaled delivery with a nebulizer or for nasal delivery.

Instant claims differ from SAIDI et al in claiming a broader scope (i.e. "any crystalline agent of any therapeutic agent" compared to SAIDI et al's specific "aerosolized corticosteroid"). It would have been obvious to one skilled in the art to prepare a method for delivery as claimed.

Rejection under 35 USC § 103(a) 1st Rejection

Claims 28-40, 42-45, and 47-59 are rejected under 35 USC § 103(a) as being unpatentable over LIVERSIDGE et al (US Patent No. 5,145,684) and FOLKE MOREN Aerosols in Medicine, Principles, Diagnosis and Therapy, (1993) Elsevier Science Publisher, Chapter 13, pages 321-350. Both references teach a method and use of drug by inhalation aerosols for drug delivery into airways that embraces Applicant's claimed invention. See the entire document.

LIVERSIDGE et al. teaches that commercial air jet milling techniques provide particles ranging in average particle size from as low as 1,000 to 50,000 nm (1 to 50 microns). The reference also teaches crystalline drug particle having a surface modifier adsorbed on the surface

thereof in an amount sufficient to maintain an effective particle size of less than 400 nm. See the entire document, especially lines 47-50 in col. 1, claims, and examples.

Instant claims differ from LIVERSIDGE et al in that the instant invention has a broader scope. LIVERSIDGE does not teach aerosols.

MOREN teaches the use of inhalation aerosols for drug delivery into airways, mainly to provide a local effect in the upper or lower respiratory tract. It also teaches that drugs are widely used for local effect in the lower respiratory tract. Bronchodilators, corticosteroids, anticholinergics and antiallergic drugs are administered by means of oral inhalation. The advantages being decreased systemic side effects, and in some cases rapid onset of action See 2nd paragraph on page 321. See also 1st and 2nd paragraphs on page 322, see nasal inhalation on page 337, particle size on page 338, see section 4.1 and 4.1.1 where aqueous aerosols are taught.

It would have been obvious to one skilled in the art at the time of invention was made to prepare the method of delivering an aerosol to lungs as claimed by the combined teachings of the two references cited above for the treatment of respiratory diseases by using aerosols because LIVERSIDGE et al teaches the average particle size, surface modifier, and all other limitations of the presently claimed invention and MOREN teaches aerosols and delivery to respiratory tract using poorly soluble drugs such as steroids.

Referring to claim 44 Applicants have not shown how the method of treating various diseases is different from the prior art teaching by using their delivery method.

In absence of any criticality and/or unexpected results instant invention is considered *prima facie* obvious to one skilled in the art.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Rejection under 35 USC § 103(a) 2nd Rejection

Claims 28-40, 42-45, and 47-59 are rejected under 35 USC § 103(a) as being unpatentable over LIVERSIDGE et al (US Patent No. 5,145,684), A.R. GENNARO Remington's Pharmaceutical Sciences, 17th Edition, (1985), Chapter 93, pages 1670-1677 and DIETER KOHLER, Aerosols in Medicine, Principles, Diagnosis and Therapy, Edited by F. Moran, Chapter 12, (1993), pages 303 319. All the references teach a method that embraces Applicant's claimed invention.

LIVERSIDGE et al. teaches that commercial air jet milling techniques provide particles ranging in average particle size from as low as 1,000 to 50,000 nm (1 to 50 microns). The reference also teaches crystalline drug particle having a surface modifier adsorbed on the surface thereof in an amount sufficient to maintain an effective particle size of less than 400 nm. See the entire document, especially lines 47-50 in col. 1, claims, and examples.

Instant claims differ from LIVERSIDGE et al in that the instant invention has a broader scope and use aerosols. LIVERSIDGE does not teach aerosols. GENNARO and KOHLER reference teaches use of aerosol for poorly soluble drugs, absorbence, particle size and various others related to aerosols.

GENNARO reference teaches pharmaceutical aerosols in the form of solutions, suspensions, emulsions, powders and semisolids, see the entire document (see especially Table V

in the left column of page 1672). The reference also teaches the preparation of aerosols for antibiotics, steroids and other difficultly soluble compounds (see last two paragraphs on page 1672 in the right column. See particle size and drug delivery into respiratory airways on pages 1674 and 1675, Table IX on page 1676 where steroids and other poorly soluble drugs are listed as medicinal agents having high potential for use as aerosol inhalation products.

KOHLER teaches the advantages of drug administration via aerosols for systemic treatment over oral routes of the compounds that are poorly soluble. See the entire document especially 2nd para on page 305, TABLE 1, section 3.1 on page 309-311, TABLE 2 and section 3.3 on page 313 and last paragraph on page 315.

It would have been obvious to one skilled in the art at the time of invention was made to prepare the method of delivering an aerosol to lungs as claimed for the treatment of respiratory diseases by the combined teachings of the above cited references, because LIVERSIDGE et al teaches the average particle size, surface modifier, and all other limitations of the presently claimed invention and GENNARO and KOHLER references teach the use of aerosols for poorly soluble drugs and inhalation products and treatment of asthma and other respiratory illness.

At the time of invention the use of aerosols was known in the art. All the claimed invention is taught by LIVERSIDGE except aerosols. It would have been *prima facie* obvious to use aerosols because prior art teaches the use for the same purpose.

Referring to claim 44 Applicants have not shown how the method of treating various diseases is different from the prior art teaching.

In absence of any criticality and/or unexpected results instant invention is considered *prima facie* obvious to one skilled in the art.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Information Disclosure Statement

The information disclosure statement filed on 5/18/05 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Qazi

SABIHA QAZI, PH.D
PRIMARY EXAMINER

Sunday August 21, 2005